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(54) **ZYGOMATIC ELEVATOR DEVICE AND METHODS**

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CPC ***A61B 17/8866*** (2013.01); ***A61B 17/025*** (2013.01); ***A61B 17/0218*** (2013.01); ***A61B 17/885*** (2013.01)

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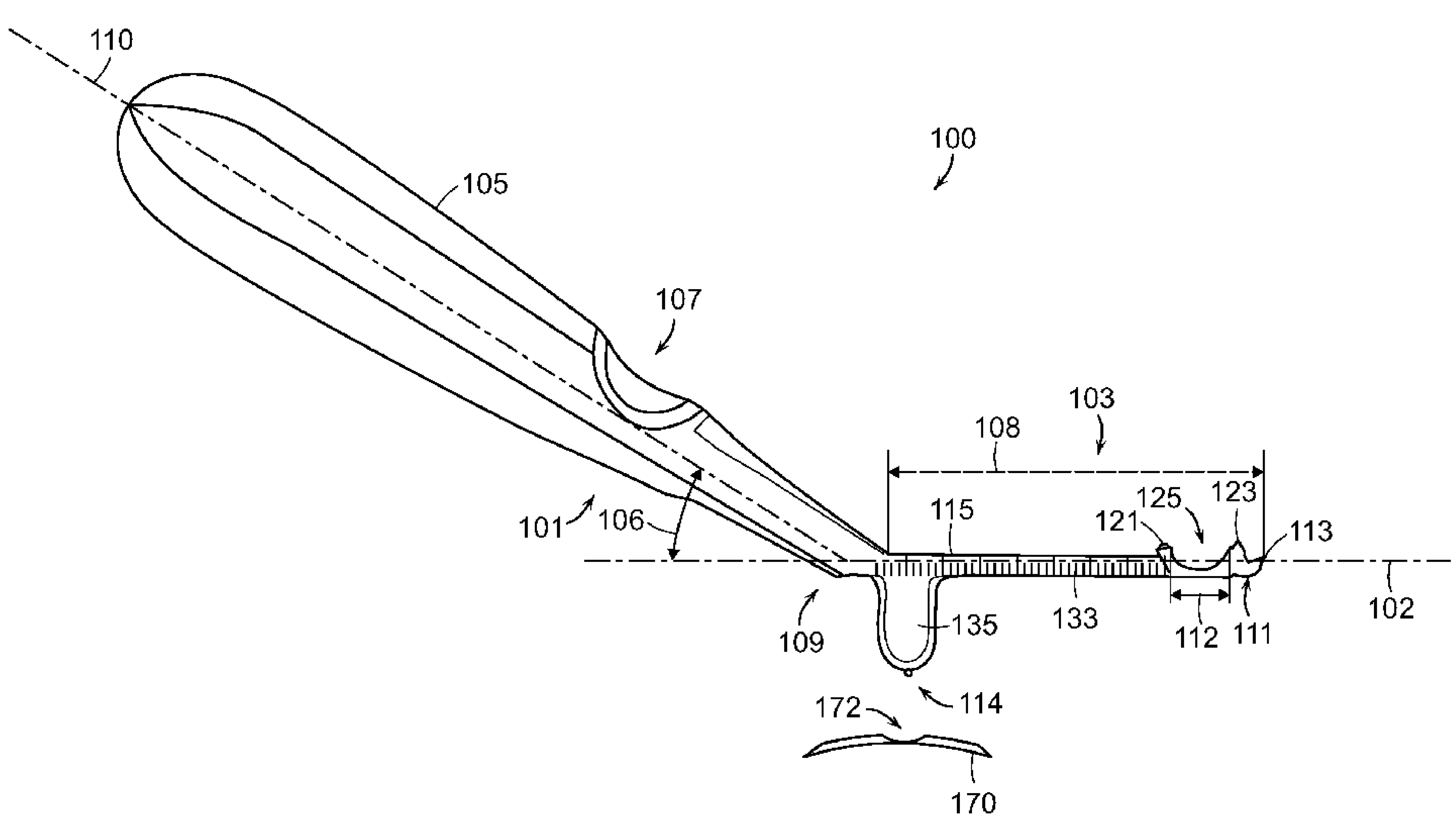
(57) **ABSTRACT**

A surgical elevator device that can be used in the reduction of bone fractures, particularly facial bone fractures, and even more particularly zygomatic arch fractures. The elevator device enables accurate measurement of the depth of insertion of the device into tissue space and provides tactile control of fracture location and reduction. In one embodiment, the elevator device comprises a groove on an elevator element for receiving a bone structure. The groove can be formed by a pair of parallel ridges. A projection extending from the elevator provides a pivot point for applying a controlled force to the bone to reduce the fracture. A preferred embodiment further comprises a method of reducing a bone fracture, such as a zygomatic arch fracture.

22 Claims, 5 Drawing Sheets



(58) **Field of Classification Search**
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USPC .... 600/201, 210, 217, 226, 235–238; 606/86 R, 87, 90, 105; D8/88, 89; 157/1.3
See application file for complete search history.

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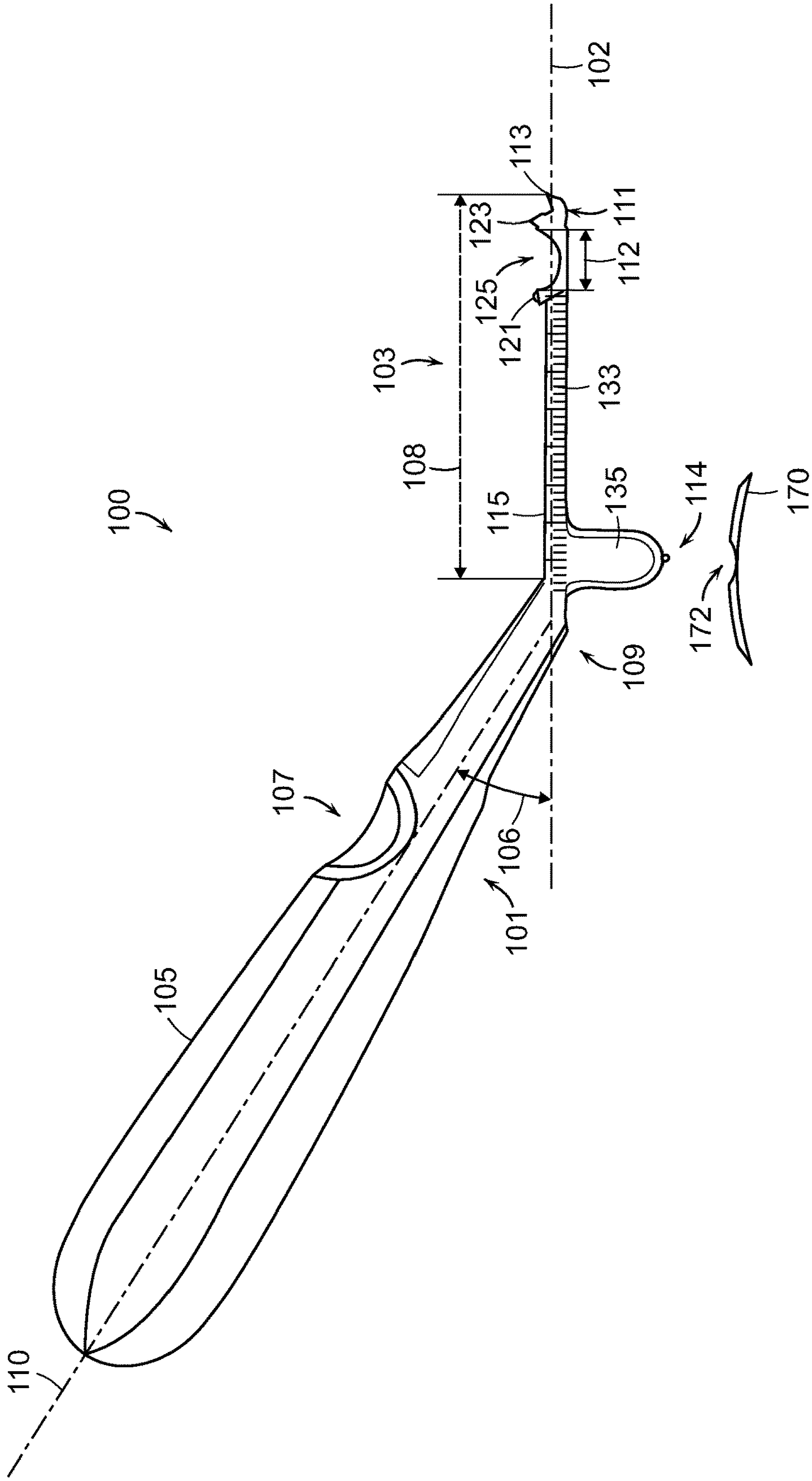
100
101
102
103
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121
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125
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135
170
172

FIG. 1

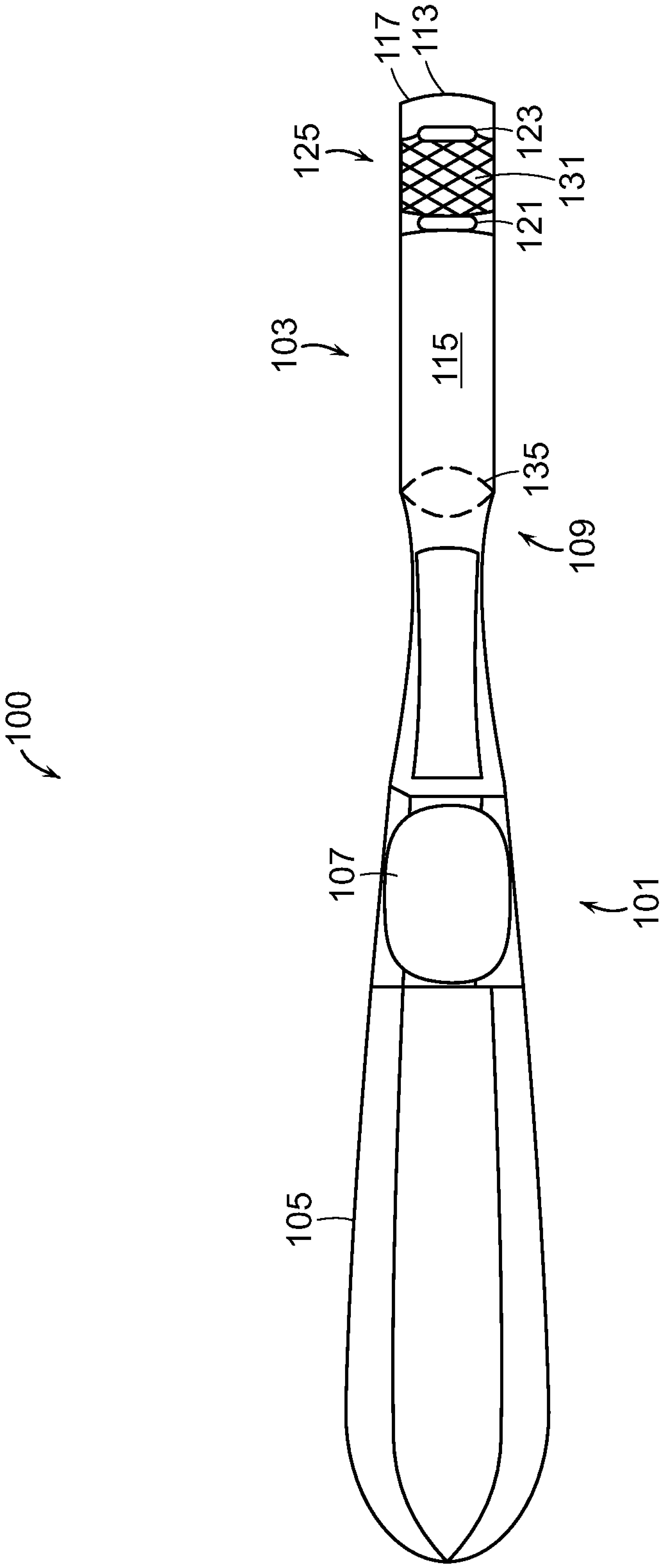

FIG. 2

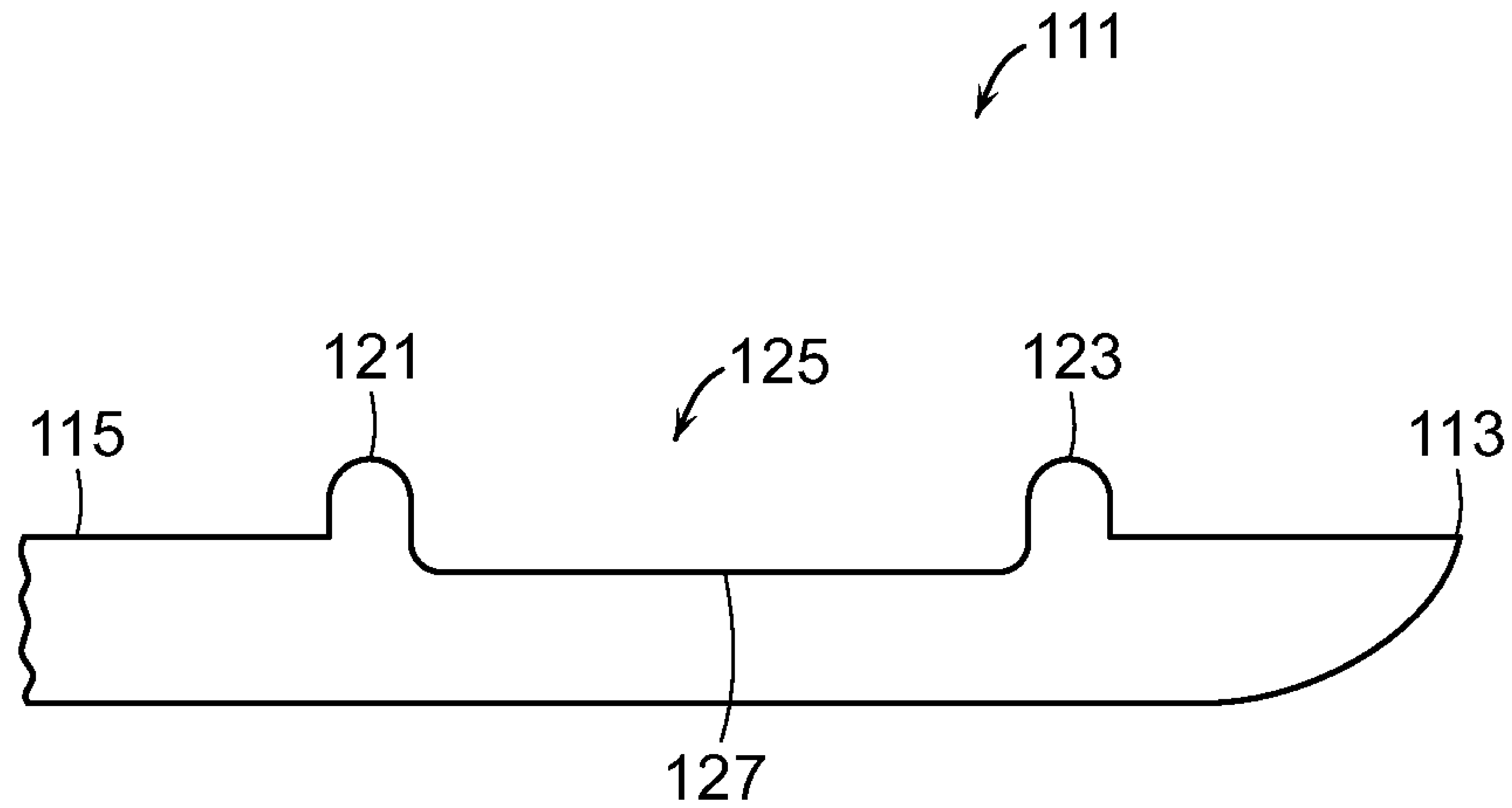
111
121
125
123
115
113
127

FIG. 3A

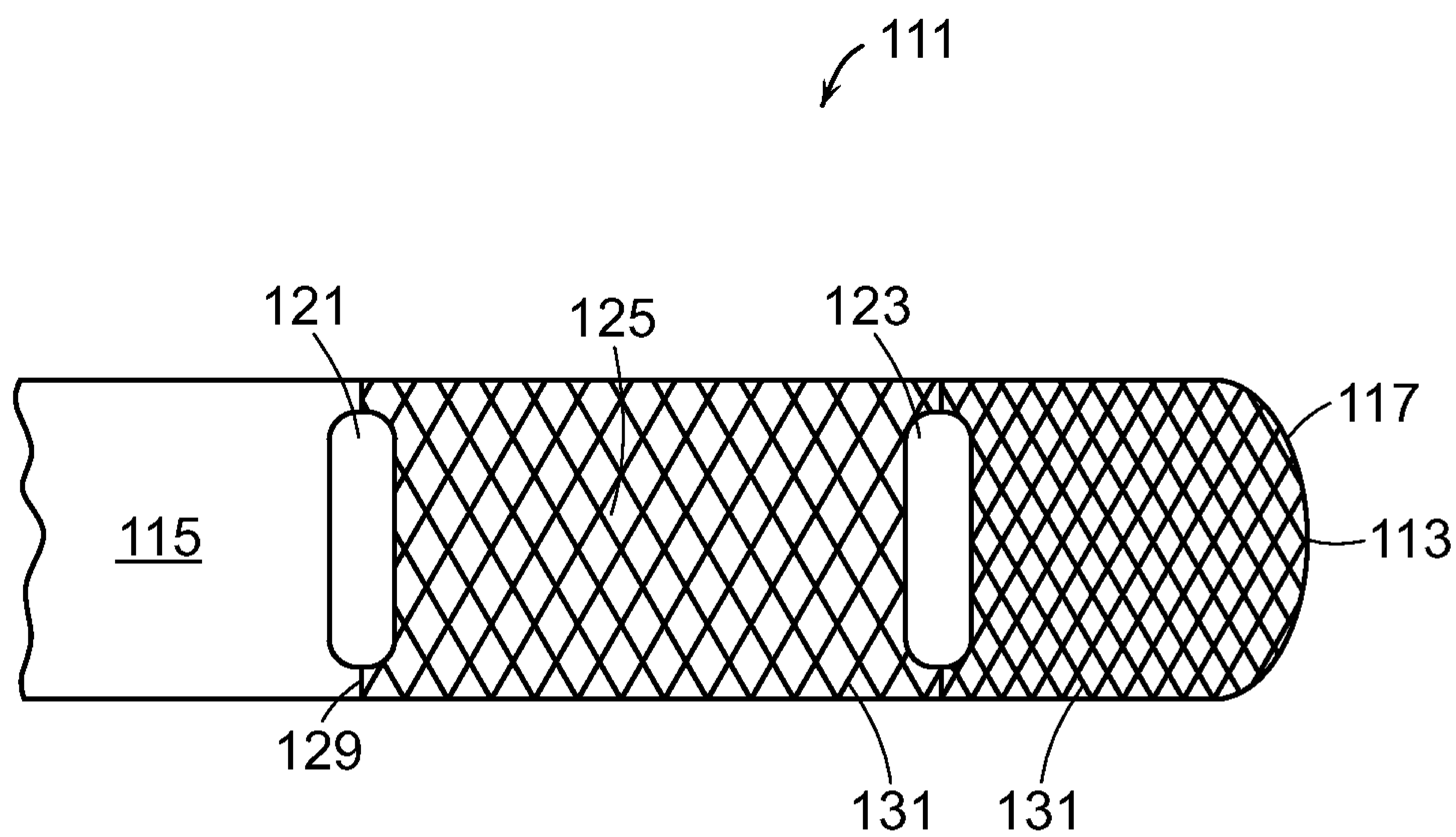
111
121
125
123
117
115
113
129
131
131

FIG. 3B

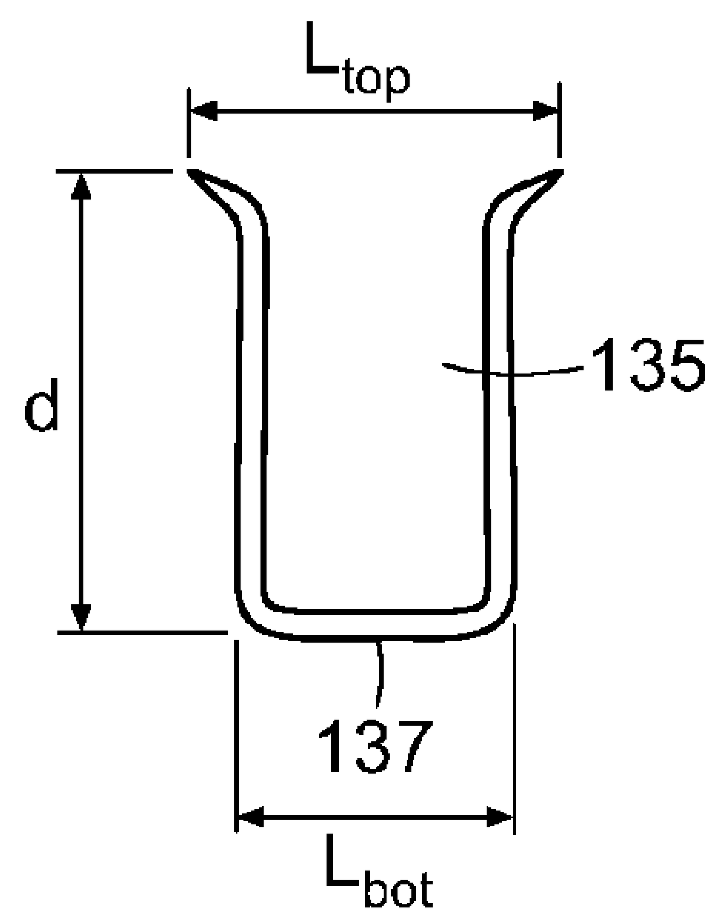

FIG. 4A

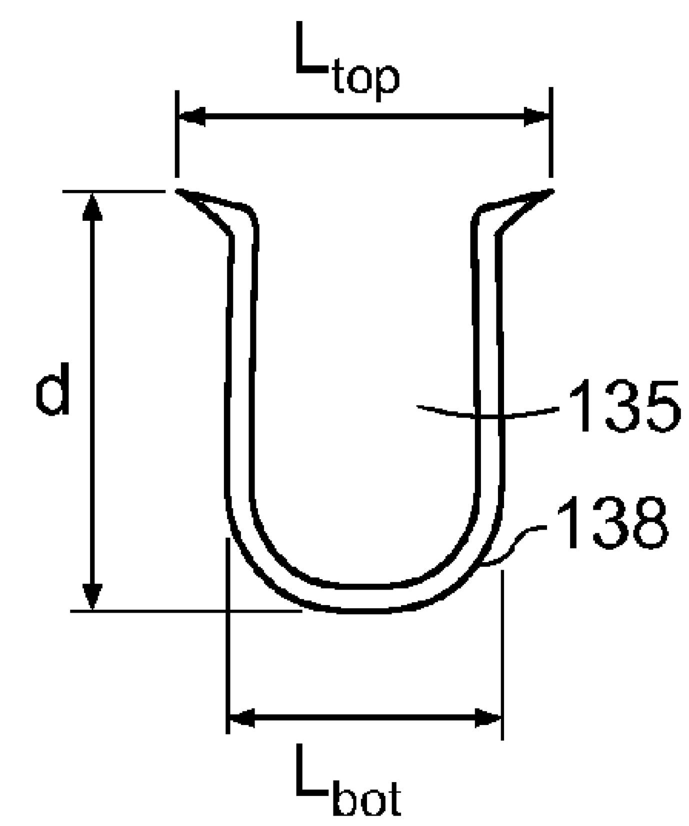

FIG. 4B

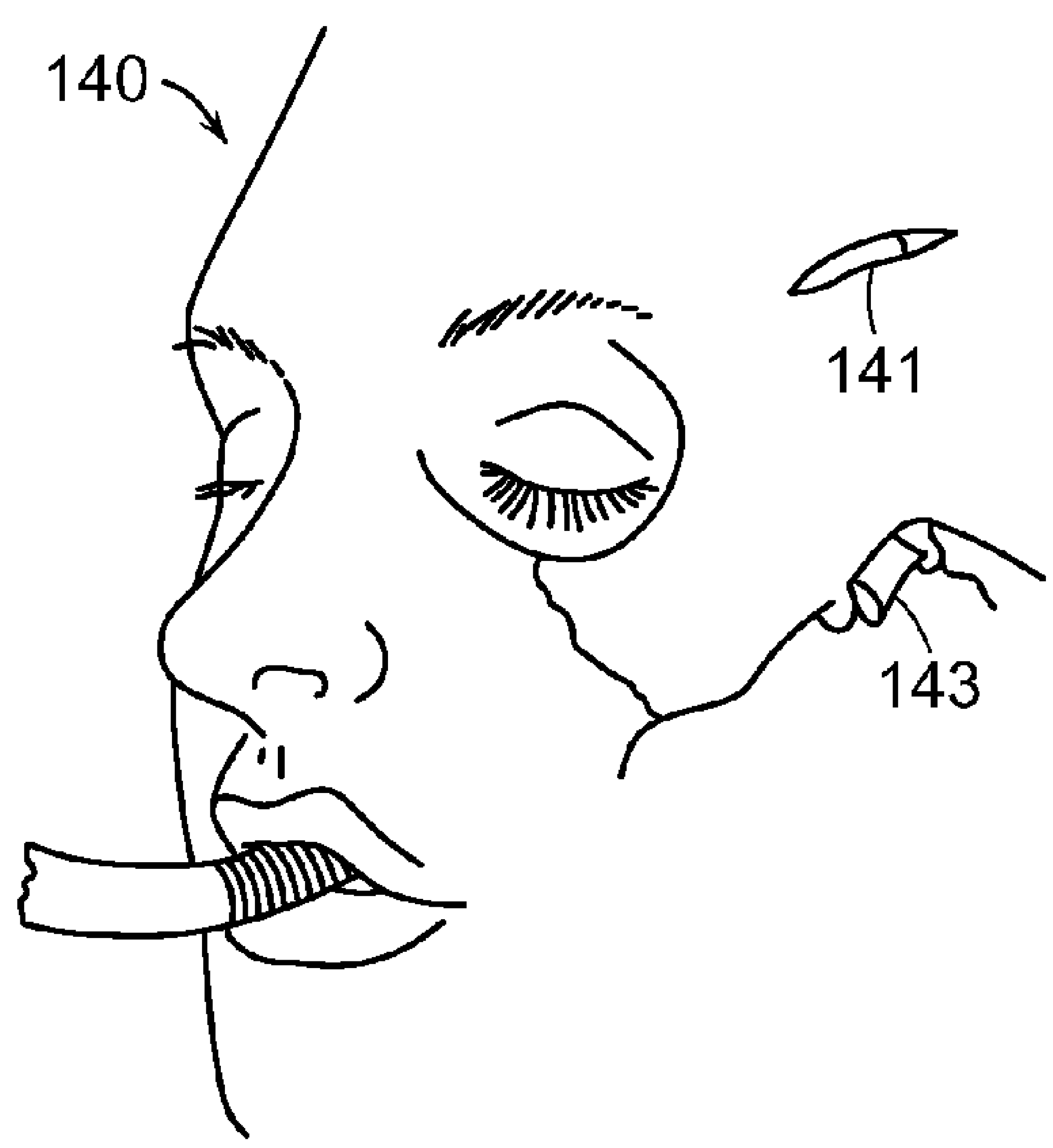

FIG. 5A

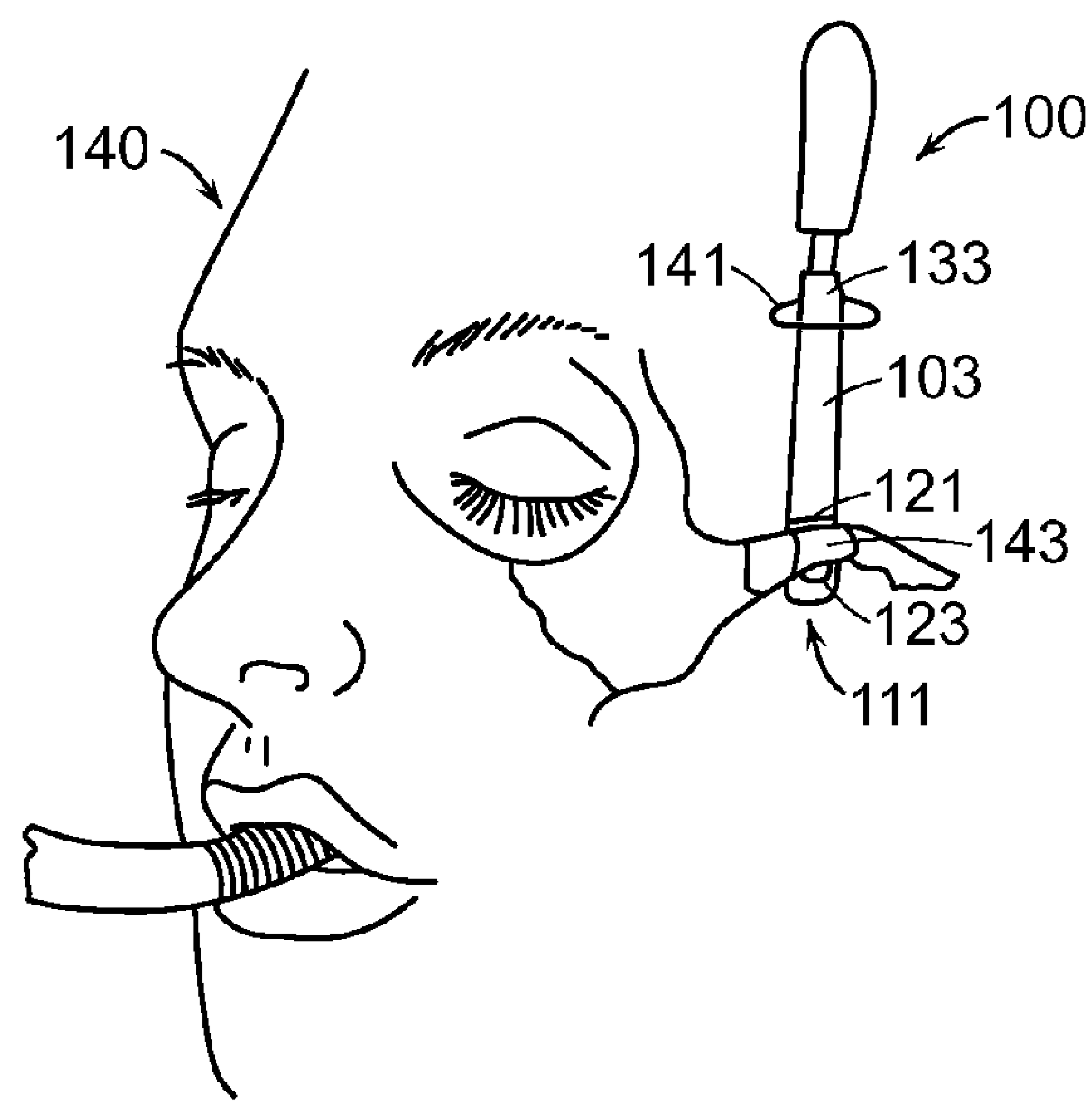

FIG. 5B

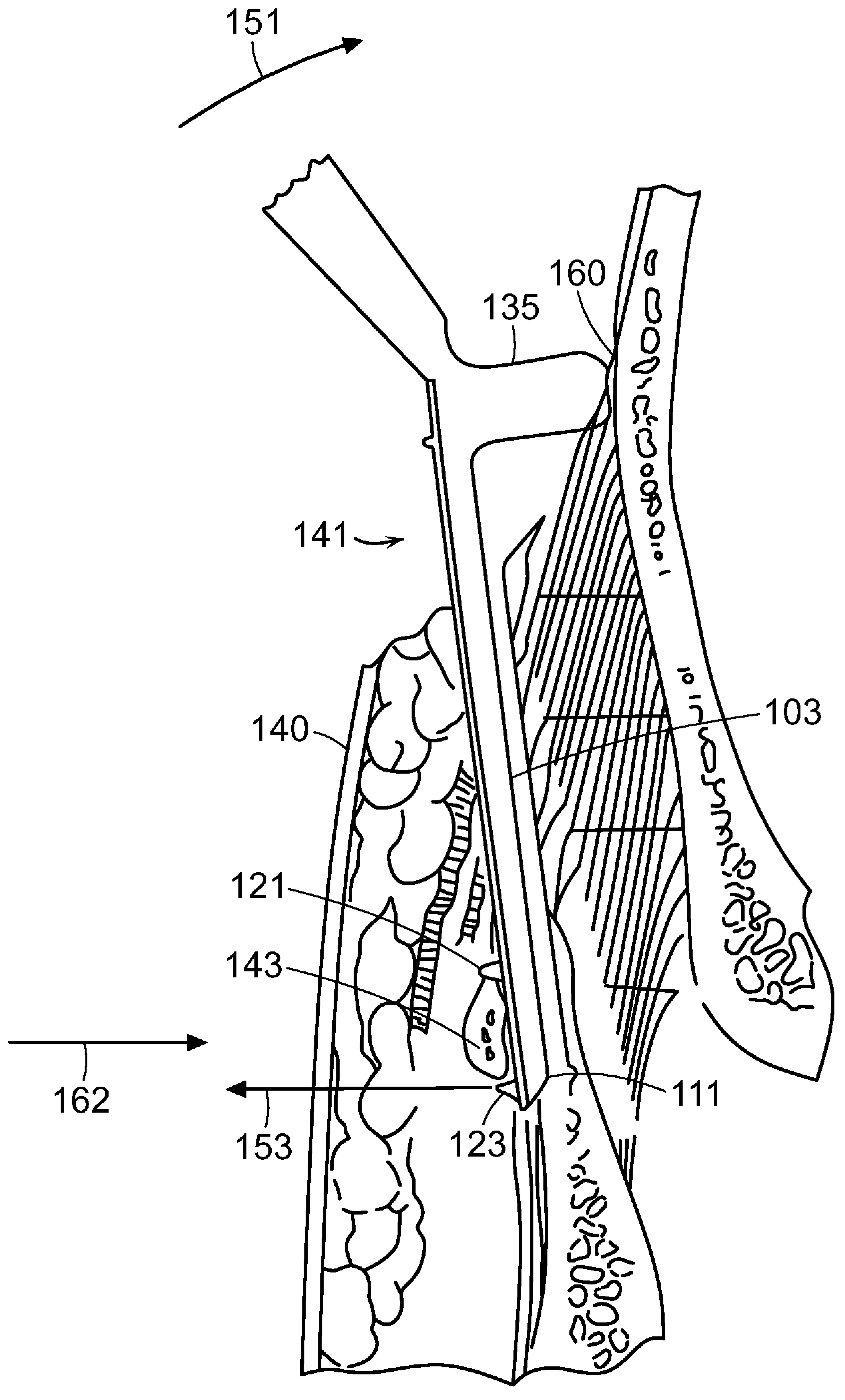

FIG. 6

ZYGOMATIC ELEVATOR DEVICE AND METHODS

CROSS REFERENCE TO RELATED APPLICATIONS

This application is 35 USC § 371 national stage filing of International Application No. PCT/US2011/027161, filed Mar. 4, 2011, which claims the priority of U.S. Provisional Application No. 61/310,950, filed on Mar. 5, 2010, the entire teachings of which are incorporated herein.

BACKGROUND OF THE INVENTION

The zygomatic arch is a bone structure located in the cheek area of the face that extends between the zygoma and the temporal bone. Because of the position and prominence of this structure, fractures of the zygomatic arch are a relatively common type of facial injury.

To treat zygomatic arch fractures, various techniques are used to re-set or "reduce" the fracture, by restoring the injured structure to its normal anatomic position. In some cases, this can be done non-invasively by a "closed reduction," in which the bone is restored by external manipulation without requiring an incision. Frequently, however, an "open reduction" is needed, which requires a surgical incision for reduction, and optional internal fixation, of the fractured zygomatic arch.

One common technique for reduction of a zygomatic arch fracture, known as the Gillies' method, involves making a small incision in the skin of the patient's head, preferably behind the hairline to minimize visible scarring, inserting a surgical elevator device behind the fractured bone, and applying a force against the bone to reduce the arch. Other similar techniques are known that involve inserting a surgical instrument, such as a bone hook, wire, towel clip, or similar device, and applying an outward force against the zygomatic arch to reduce the fracture.

SUMMARY OF THE INVENTION

The present invention comprises a surgical elevator device that can be used in the reduction of bone fractures, particularly facial bone fractures, and even more particularly zygomatic arch fractures. The present elevator device enables accurate measurement of the depth of insertion of the device into position adjacent the skeletal feature of interest, provides tactile control of fracture location and reduction, and permits improved control of the magnitude and direction of the force applied to reduce fractures.

In the existing techniques for reduction of zygomatic arch fractures, using a Rowe zygoma elevator, a bone hook or the like, the successful outcome of the procedure is largely dependent on the skill and technique of the surgeon performing the procedure. With existing techniques, it is often difficult to correctly control the location of the elevator device relative to the fracture, as well as the magnitude and direction of the force applied to reduce the fracture.

According to one embodiment of the present invention, a surgical elevator device comprises a elevator element that is inserted under the bone, the elevator element having a distal end and a proximal end, an upper surface. A handle for gripping the elevator device is attached to the proximal end of the elevator element. A groove for receiving a bone structure, the groove being located on a first (upper) surface of the distal portion of the elevator element portion; and a base on a second surface of the elevator device. The groove can be formed by a pair of projections, such as parallel ridges on the first elevator surface, and can provide the surgeon with tactile control of the fracture location in relation to the elevator element. The base can extend substantially unidirectionally from the second surface of the elevator, such as the bottom surface of the elevator element, and provides a pivot point for rotation about an axis to enable the transfer of a controlled force from the handle portion to a bone structure within the groove. In one preferred embodiment, the groove is configured and sized to receive a portion of a zygomatic arch, and the controlled force directed away from the patent comprises a lateral outward force to reduce a zygomatic arch fracture. The base can be configured to be placed against an extraoral anatomic feature, such as the temporal bone of the patent to provide a fulcrum.

In further embodiments, the elevator device includes markings on the elevator element to indicate the depth of insertion of the elevator element into a subject. The portion can include a roughened surface, such as serrations, on the distal end to help prevent the elevator element from slipping against the bone structure. The handle portion is preferably oriented at an angle with respect to the elevator element.

According to yet another embodiment, a method of reducing a fractured bone using a surgical elevator device comprises making an incision over the temporal bone to enable percutaneous insertion of the elevator element into a subject by manipulating a handle portion of the elevator device; positioning a distal end of the elevator element beneath the fractured bone so that the bone is received by a groove on the first surface; positioning a base extending from a surface of the elevator device against an (extraoral) external surface feature of the subject to provide a pivot point; and rotating the handle towards the subject, using the projection as a pivot, to transfer a substantially lateral outward force to the fractured bone positioned in the groove to reduce the fracture. The user, such as a surgeon, can simultaneously palpate the external surface of the tissue overlying the bone. In a preferred embodiment, the fractured bone comprises a zygomatic arch.

BRIEF DESCRIPTION OF THE DRAWINGS

Various aspects of at least one embodiment of the present invention are discussed below with reference to the accompanying figures. In the figures, which are not intended to be drawn to scale, each identical or nearly identical component that is illustrated in the various figures is represented by a like numeral. For purposes of clarity, not every component may be labeled in every drawing. The figures are provided for the purposes of illustration and explanation and are not intended as a definition of the limits of the invention. In the figures:

FIG. **1** is a side view of an elevator device according to one embodiment of the invention;

FIG. **2** is a top view of the elevator device of FIG. **1**;

FIG. **3**A is a side view of the tip end of the elevator device;

FIG. **3**B is a top view of the tip end of the elevator device;

FIG. **4**A illustrates a projection of an elevator device of the invention;

FIG. **4**B illustrates an alternative embodiment of the projection;

FIGS. **5**A and **5**B illustrate a surgical procedure using the elevator device of the invention to reduce a zygomatic arch; and

FIG. **6** illustrates a cross-sectional view of a preferred embodiment of an elevator device used to reduce a zygomatic arch fracture.

DETAILED DESCRIPTION OF THE INVENTION

Referring now to FIGS. **1-4**B, an elevator device **100** for use in a surgical procedure, for instance, for the reduction of a zygomatic arch fracture, is illustrated. The elevator device **100** generally includes a handle portion **101** and a elevator element **103**. The elevator element portion **103** can be angled with respect to the handle portion **101**, such as shown in the side-view of FIG. **1**. This angle **106** can be between 20 and 70 degrees, preferably in a range of 30 to 60 degrees. The angle **106** between the handle axis **110** and the elevator axis **102** is thus preferably at least 20 degrees to provide sufficient clearance from the head of the user. The handle portion **101** can include a grip **105** that allows the device **100** to be easily grasped and manipulated by a user. The grip **105** can further include a groove **107** that is positioned to receive the thumb of a user for more precise control of the device **100**.

The elevator element **103** includes a proximal end **109**, where the element **103** connects to the handle portion **101**, and a distal end **111** terminating at a tip **113**. The portion **103** can have a generally flat upper surface **115**. The upper surface **115** of the portion **103** is generally between about 40 and 60 mm in length, and in one embodiment is about 50 mm in length. Several different lengths can be housed in a kit for use with different feature sizes. As is illustrated in the top view of FIG. **2**, the width of the portion **103** has a length **108** that is generally between about 10 and 15 mm, and in one embodiment is about 12 mm. The sides of the tip **113** can be rounded over as shown in FIG. **1**, and form a slightly-curved edge **117** (FIG. **2**) where the tip **113** meets the distal end of the flat upper surface **115**. The tip **113** can have a sharp edge to aid with insertion.

FIGS. **3**A and **3**B are side and top views, respectively, of the distal end **111** of the portion **103**, showing several features of the elevator device **100** in greater detail. The upper surface **115** of the portion **103** include a pair of parallel raised ridges **121**, **123**. The ridges **121**, **123** define a groove **125** that is preferably sized and shaped to receive an anatomical structure, such as the bone or bone fragments of a fractured zygomatic arch. The ridges **121**, **123** and the groove **125** can help stabilize the anatomical structure while the elevator **100** is used to apply an outward lateral force against the structure. In one embodiment, the groove **125** further includes a depression **127** in the upper surface **115** of the elevator element. The depression **127** can extend over the entire groove **125** region between the ridges **121**, **123**, as shown in FIG. **3**A.

The ridges **121**, **123** can extend across the entire width of the elevator portion **103**, or, as shown in FIG. **3**B, the ridges **121**, **123** can extend over a portion of the width of the portion. In the embodiment of FIGS. **3**A and **3**B, for example, the ridges **121**, **123** are each between about 6 and 10 mm in length, with a gap **129** of between about 1 and 2 mm between the end of each ridge **121**, **123** and the edge of the blade portion **103**. The proximal ridge **121** (i.e., closest to the handle portion **101**) is preferably located about 5 to 10 mm from the tip **113** of the elevator portion **103**, and the distal ridge **123** (i.e., closest to the blade tip **113**) is preferably about 1 to 4 mm from the tip **113**.

The upper surface **115** of the portion **103** preferably includes serrations **131** or a similar surface roughening extending over at least the distal end **111** of the portion **103**. The serrations **131** preferably extend at least over the surface of the groove **125** between the ridges **121**, **123**, and preferably also extend from the distal ridge **123** to the tip **113** of the portion **103**. The groove **125** can have a length **112** generally in a range of 2-8 mm. The serrations **131** increase the surface area of the elevator element and increase the frictional forces between the elevator and any tissue or anatomical structures contacting the elevator, and thus helps prevent the elevator from slipping relative to an anatomical structure, such as a zygomatic arch, during a surgical procedure, such as a fracture reduction. As shown in FIG. **3**B, the serrations **131** can be in two sections, with a first serrated surface in the groove **125**, and a second surface having finer serrations proximate the tip **113**.

The elevator device **100** can further include markings **133**, such as metric units (millimeters) on the portion **103** of the device, as shown in FIG. **1**, that can aid the user in determining the depth of insertion when the elevator device **100** is inserted into a patient.

Turning now to FIGS. **1** and **4**A, according to one embodiment, the elevator device **100** includes a projection **135** that extends from the bottom side at a proximal end of the elevator portion **103**. In a preferred embodiment, the projection can extend "unidirectionally," meaning that where the upper surface **115** of the blade portion **103** defines a plane, the projection **135** extends in one direction relative to the plane. Conversely, the handle portion **101** can extend unidirectionally in an opposite direction relative to the plane. The projection **135** is preferably located at or near the proximal end **109** of the portion **103**. The projection **135** can be a ridge structure with a substantially rectilinear cross-section, such as shown in FIGS. **1** and **4**A. In other embodiments, such as shown in FIG. **4**B, the projection **135** can comprise a generally curved surface **138** extending from the bottom of the portion **103**. Other shapes can be used for the projection **135**.

The projection **135** can extend down from the portion **103** a distance, d, of between about 8 and 15 mm, and preferably about 12-14 mm. The projection **135** can have a width of between about 6 and 15 mm, and preferably extends across most or all of the width of the portion **103**, as shown in phantom in FIG. **2**. In the embodiment of FIG. **4**A, the generally flat bottom surface of the projection **135** with area **137**, has a length, L_{bot}, that is between about 5 and 15 mm, and is preferably about 8 mm. The projection **135** can be tapered to be wider at its top, where the projection **135** meets the portion **103**, and narrower at its bottom surface. In the embodiment of FIGS. **1** and **4**A, for example, the projection **135** can have a length, L_{top}, of about 5 and 20 mm long at its top, and is preferably about 11 mm.

According to one aspect, the projection **135** comprises a unidirectional member that provides a fulcrum, such that by rotating the handle portion **101** in a first direction, with the end **114** of the projection **135** serving as a fixed pivot point, the distal end **111** of the elevator element **103** is caused to move in an arcuate motion in a second, opposing direction. An advantage of this design is that during an invasive medical procedure, such as reduction of a zygomatic arch fracture, the user is able to more precisely control the magnitude and direction of the outward lateral force applied to the patient by the elevator device **100**.

FIGS. **5**A and **5**B illustrate the elevator device **100** of the present invention being used for a medical procedure, specifically, a reduction of a zygomatic arch fracture. As shown in FIG. **5**A, a small incision **141** (e.g., 2 cm) is made in the skin of a patient **140** in the vicinity of the fractured zygomatic arch **143**, as is known in standard medical techniques for reduction of a zygomatic arch fracture (e.g., the Gillies' method, etc.). The incision is preferably made percutaneously on an external surface on the side of the patient's head, for example, in the temporal fossa or orbital regions. In one embodiment, a temporal incision is made through the superficial fascia and subcutaneous tissue and into the deep temporal fascia that overlays the temporalis muscle. The superficial fascia and subcutaneous tissue can be retracted. An incision can be made through the deep temporal fascia to expose the temporalis muscle and the temporal bone.

Next, as shown in FIG. **5**B, the elevator device **100** of the present invention is inserted through the incision **141**, with the surgeon manipulating the device **100** until the distal end **111** of the portion **103** is positioned between the fractured bone and the underlying anatomy. In one embodiment, the elevator device **100** passes between the deep temporal fascia and the underlying temporalis muscle and temporal bone. The distal end **111** of the elevator passes between the zygomatic arch and the coronoid process. The surgeon can use manual palpitation of the arch structure **143** to determine its position relative to the incision **141** point, and the graduated markings **133** on the elevator device **100** can determine the depth of insertion of the elevator device and consequently aid the surgeon in properly positioning the distal end **111** of the portion **103** under the fractured bone. As shown in FIG. **6**, the elevator device **100** is positioned such that the fractured arch **143** lies between the parallel ridges **121**, **123** of the elevator, and is received within the groove **125** formed between the ridges **121**, **123**. The ridges **121**, **123** can further provide the surgeon with a tactile feedback of the position of the elevator with respect to the fractured bone. The serrations **131** (FIG. **3**B) can help prevent the blade and bone from sliding relative to one another.

To reduce the fracture, the surgeon places the projection **135** against an anatomic feature of the patient, and rotates the handle portion **101** downwards (i.e., towards the patient). In a preferred embodiment, the projection **135** is placed against an extraoral anatomic feature of the patient, such as a bone or muscle. In one embodiment, the projection **135** is placed against the temporal bone at **160** where the incision **141** has exposed a portion thereof. The projection **135** acts as a fixed pivot point, and transfers the force of the rotation of the handle portion **101** towards the patient (see arrow **151**) into a substantially lateral outward force (see arrow **153**) at the distal end **111** of the portion **103**. The substantially lateral outward force **153** of the portion **103** acts on the arch structure **143** to reduce the fracture. The surgeon can manually exert a counterforce **162** to the same region to control the application of force. The size of the surface area on the bottom of projection **135** can be enlarged to distribute the force. A separate plate **170** can be placed over the incision with a recess **172** to receive the base projection **135** which distributes the force to a larger area. After the fracture is reduced, the elevator device **100** is withdrawn through the incision **141**, and the incision **141** can be closed.

Although the present elevator device is described herein in connection with the reduction of a zygomatic arch fracture, it will be understood that the present elevator device can be used for other surgical procedures on human and non-human (mammalian) subjects.

The elevator device **100** of the present invention can be made of one or more surgical-grade materials, including a metal such as stainless steel, for example which can be readily sterilized for further use. Alternatively, the device can be made of a rigid plastic material and disposed of after a single use. In a preferred embodiment, the elevator device **100** can be a single, unitary piece, Alternatively, the elevator device **100** can be assembled from a plurality of separate components to provide a composite structure, such as a plastic handle, to facilitate gripping thereof by the hand of the surgeon which can be detached for use with different size elevator elements.

While the invention has been described in connection with specific methods and apparatus, those skilled in the art will recognize other equivalents to the specific embodiments herein. It is to be understood that the description is by way of example and not as a limitation to the scope of the invention and these equivalents are intended to be encompassed by the claims set forth below.

I claim:

1. A surgical zygomatic elevator device, comprising:

an elevator element having a distal end, a proximal end, an upper surface between the distal end and the proximal end having a length between about 40 mm and 60 mm and a first axis extending longitudinally through the elevator element, the elevator element having a size for insertion through a surgical incision;

a handle sized to manually grasp the elevator device, the handle being positioned at the proximal end of the elevator element, the handle having a second axis that extends longitudinally through the handle, the handle being positioned at an oblique angle extending above the first axis of the elevator element;

a groove configured to receive a zygomatic bone structure of a patient, the groove being located on the upper surface of the elevator element and having at least one ridge spaced from the distal end of the elevator element; and

a projection extending between about 8 mm and 15 mm from a bottom surface of the elevator element, the projection being positioned at a proximal portion of the elevator element that is spaced apart from the groove, the projection being configured to contact an anatomical structure to provide a pivot point such that the elevator element can impart a controlled force in a first direction on the zygomatic bone structure that is positionable within the groove and the projection imparts a second force to the anatomical structure.

2. The surgical elevator device of claim **1**, wherein the at least one ridge further comprises a pair of parallel ridges on the upper surface of the elevator element, a gap between the parallel ridges forming the groove.

3. The surgical elevator device of claim **2**, wherein the gap is configured to receive a zygomatic arch structure.

4. The surgical elevator device of claim **1**, wherein the upper surface comprises a flat plane and a depressed surface region of the elevator element that forms the groove.

5. The surgical elevator device of claim **1**, wherein the projection has a substantially rectilinear cross-section.

6. The surgical elevator device of claim **1**, wherein the projection has a substantially curved cross-section.

7. The surgical elevator device of claim **1**, further comprising markings on the elevator element to indicate a depth of insertion of the elevator device into a mammalian subject.

8. The surgical elevator device of claim **1**, wherein the elevator element has a width of between about 10 and 15 mm.

9. The surgical elevator device of claim **1**, wherein the groove is less than about 10 mm from a tip of the elevator element.

10. The surgical elevator device of claim 1, wherein the first axis has an angle of at least 20 degrees with respect to the second axis extending through the handle.

11. The surgical elevator device of claim 1, wherein the elevator element includes a rough surface region over at least the distal end of the elevator element.

12. The surgical elevator device of claim 11, wherein the rough surface region comprises serrations.

13. The surgical elevator device of claim 1, wherein the device is insertable into a mammalian body, and the controlled force comprises a lateral outward force for reducing a zygomatic bone fracture.

14. The surgical elevator device of claim 1, wherein the projection extends from the bottom surface at the proximal end of the elevator element.

15. The surgical elevator device of claim 1, wherein the elevator device is an extraoral surgical device.

16. The surgical elevator device of claim 15, wherein the projection is configured to be placed against an extraoral anatomic feature of a patient to provide a fulcrum.

17. The surgical elevator device of claim 16, wherein the extraoral anatomic feature comprises an orbital region.

18. The surgical elevator device of claim 1, wherein the projection is placed to press against a temporal bone.

19. The surgical elevator device of claim 1, wherein the handle extends at an angle relative to the elevator element, and in a direction opposite the direction of the projection relative to a plane of the upper surface.

20. The device of claim 1 wherein the projection is positioned at the proximal end of the elevator element such that the projection is placed to press against a temporal bone.

21. A zygomatic elevator device, comprising:

an elevator element having a distal end, a proximal end, an upper surface between the distal end and the proximal end having a length between about 40 mm and 60 mm and a first axis extending through the elevator element;

a handle sized to manually grasp the elevator device, the handle being positioned at the proximal end of the elevator element, the handle having a second axis positioned at an oblique angle extending above the upper surface of the elevator element;

a groove configured to receive a zygomatic bone structure, the groove being located on the upper surface of the elevator element, and having at least one ridge spaced from the distal end of the elevator element by a predetermined distance;

a projection extending between about 8 mm and 15 mm from a bottom surface of the elevator element, the projection being proximal to, and spaced from, the groove, wherein the projection is positioned at a proximal portion of the elevator element and configured to contact an anatomical structure that is separated from the groove by a distance to provide a pivot point such that the elevator element can impart a force on the zygomatic bone structure that is positionable within the groove while the projection imparts a second force to the anatomical structure.

22. The device of claim 21 further comprising a second ridge parallel to the at least one ridge, wherein a gap between the at least one ridge and the second ridge forms the groove to receive the zygomatic bone structure.

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